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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,403	03/30/2006	Graham Cotton	08830-0390US1	2290

23973 7590 10/23/2008
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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10/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,403	Applicant(s) COTTON, GRAHAM	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18-21, 23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 8, 12, 14, 20, 23, 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9-11, 13, 15 and 21 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 6, 7, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2008 has been entered.
2. Claims 18, 19, and 21 are objected to because of the following informalities: In claim 18, the last three lines should be deleted because they recite a proviso which only concerns the deleted Formula II. In claim 21, the amendment marking has gone through rather than below the inserted Formula II. This should be corrected in the next submission of a Listing of Claims. In claim 21, last four lines, the phrase "where said label molecule and the oligopeptide are linked via a linking moiety having Formula II" is redundant to step (c), which requires the linking moiety to have Formula II. The phrase should be deleted. In claim 21, last four lines, the phrase "and where said activated ester moiety of said label is not a thioester moiety, said activated ester moiety is a terminally activated ester moiety" contradicts the immediately following phrase in the claim which specifies that the activated ester moiety is a thioester moiety, and therefore the quoted phrase should be deleted. Appropriate correction is required.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by the Vanderesse et al article (J. Peptide Sci., Vol. 9, pages 282-299). The Vanderesse et al article teaches hexapeptide 23a (see Scheme 7) in which two peptides, Ala-Ala-Pro and Ala-Ala, are linked via a linking moiety -C(O)-NH-O-. Note that the claim does not specify any particular point of attachment

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between the linking moiety and the C-terminal peptide. Further, process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

5. Claims 1, 5, 11, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by the Vanderesse et al article (J. Peptide Sci., Vol. 9, pages 282-299) as applied against claim 15 above, and further in view of Alpegiani et al (U.S. Patent No. 6,194,451). The Vanderesse et al article teaches forming hexapeptide 23a in Scheme 7 by reacting Z-Ala-Ala-Pro with $\text{NH}_2\text{-O-CH-Pr-CO-Ala-Ala-NH-Pr}$ in the presence of DIEA, TBTU, HOBt, and DMF, but does not describe that the Z-Ala-Ala-Pro is in the form of an activated ester. Alpegiani et al at column 13, line 62 - column 14, line 2, teach that activated esters with HOBt can be obtained and reacted in situ by use of a condensing agent including TBTU. Because the Vanderesse et al article reacts Z-Ala-Ala-Pro in the presence of HOBt and TBTU, then in view of the teaching of Alpegiani et al, it is seen that inherently the reaction of the Vanderesse et al article will proceed through the formation of an activated ester of Z-Ala-Ala-Pro, and Applicant's claim requirement for a second oligopeptide having an activated ester moiety is inherently met by the Vanderesse et al article. Note that Applicant's claims do not specify how the activated ester of the second oligopeptide is to be formed, and do not require the activated ester to be formed prior to mixing the second oligopeptide with the first oligopeptide. With respect to instant claim 21, the Z-Ala-Ala-Pro of the Vanderesse et al article, upon mixing with the HOBt and TBTU and forming the activated ester, corresponds to Applicant's label molecule. Note that Applicant's claims do not set forth any structural and/or functional limitations on the identity of the label molecule.

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6. Claims 9, 10, and 13 are rejected under 35 U.S.C. 103(a) as being obvious over the Vanderesse et al article (J. Peptide Sci., Vol. 9, pages 282-299) in view of Alpegiani et al (U.S. Patent No. 6,194,451). Application of the Vanderesse et al article and Alpegiani et al is the same as in the above rejection of claims 1, 5, 11, and 21. The Vanderesse et al article does not teach forming the Ala-Ala-Pro and/or Ala-Ala oligopeptides recombinantly. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to form the Ala-Ala-Pro and/or Ala-Ala oligopeptides of the Vanderesse et al article recombinantly, because recombinant synthesis of peptides is well-known in the art, and the method of forming a peptide would have no effect on the ability of the peptide to undergo the reactions used to form the hexapeptide 23a of the Vanderesse et al article. The Vanderesse et al article does not teach a pH for its reaction step of forming the hexapeptide 23a. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal pHs for the reaction step of the Vanderesse et al article, because pH is an art-recognized result-effective variable which is routinely determined and optimized in the chemical arts.

7. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by the Salvadori et al article (Int. J. Peptide Protein Res., Vol. 18, pages 393-401). The Salvadori et al article teaches an aminoxy analog of Leu-enkephalin, having the formula Tyr-Gly-OGly-Phe-Leu (see page 393, column 2, compound b), and Scheme 1). The OGly residue has a formula -NH-O-CH₂-CO- and when connected N-terminally to the Tyr-Gly dipeptide residue forms a -C(O)-NH-O- linking moiety. Note that the claim does not specify any particular point of attachment between the linking moiety and the C-terminal peptide. Further, process limitations do not impart

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patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

8. Claims 4, 8, 12, 14, 20, 23, 25, and 26 are allowed.

Claims 2, 3, 6, and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18 and 19 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
October 22, 2008